CLAIMS

1. A disposable test strip for use in a test meter ~~of the type~~ which receives a disposable test strip and a sample of blood and performs an electrochemical analysis of the amount of a blood analyte in the sample, comprising:

(a) a substrate;

(b) a first conductive element disposed on the substrate;

(c) a second conductive element disposed on the substrate in sufficient proximity to the first conductive element to allow the completion of an electrical circuit between the first and second conductive elements when a sample of blood is placed on the test strip;

(d) a non-conductive integrated reagent/blood separation layer disposed over the first conductive element, said integrated reagent/blood separation layer comprising reagents for the electrochemical detection of the analyte dispersed in a non-conductive matrix effective to exclude blood cells from the surface of the first conductive element while permitting access to the first conductive ~~species~~ element by soluble electroactive species; and

(e) contacts for making an electrical connection between the first and second conductive elements and the test meter.

2. The test strip of claim 1, wherein the integrated reagent/blood separation layer comprises an enzyme for oxidation of glucose and a redox mediator effective to transfer electrons from the enzyme to the first conductive element.

3. The test strip of claim 2, wherein the matrix comprises silica having both hydrophobic and hydrophilic surfaces.

4. The test strip of claims 3, wherein the first and second conductive elements comprise conductive carbon.

5. The test strip according to claim 4, wherein the enzyme is glucose oxidase.

6. The test strip according to claim 5, wherein the redox mediator is ferricyanide.

7. The test strip according to claim 3, wherein the integrated reagent/blood separation layer is formed from an aqueous composition comprising 2 to 10 % by weight of a binder; 3 to 10 % by weight of silica; 8 to 20 % by weight of the redox mediator; and 1000 to 5000 units of the enzyme per gram of the aqueous composition.

8. The test strip of claims 7, wherein the first and second conductive elements comprise conductive carbon.

9. The test strip according to claim 7, wherein the enzyme is glucose oxidase.

10. The test strip according to claim 9, wherein the redox mediator is ferricyanide.

11. The test strip of claim 1, further comprising an insulation layer disposed over at least the first conductive elements, said insulation layer having a first aperture therein aligned with the first conductive element, wherein the non-conductive

integrated reagent/blood separation layer contacts the first conductive element through the aperture in the insulation layer.

12. The test strip of claim 11, wherein the non-conductive integrated reagent/blood separation layer is formed covering the entire first aperture, thereby leaving no portion of the first conductive element directly exposed to a sample applied to the test strip.

13. The test strip of claim 12, wherein the integrated reagent/blood separation layer comprises an enzyme for oxidation of glucose and a redox mediator effective to transfer electrons from the enzyme to the first conductive element.

14. The test strip of claim 13, wherein the matrix is formed from silica having both hydrophobic and hydrophilic surfaces.

15. The test strip of claims 14, wherein the first and second conductive elements comprise conductive carbon.

16. The test strip according to claim 15, wherein the enzyme is glucose oxidase.

17. The test strip according to claim 16, wherein the redox mediator is ferricyanide.

18. The test strip according to claim 12, wherein the integrated reagent/blood separation layer is formed from an aqueous composition comprising 2 to 10 % by weight of a binder; 3 to 10 % by weight of silica; 8 to 20 % by weight of the

redox mediator; and 1000 to 5000 units of the enzyme per gram of the aqueous composition.

19. The test strip of claims 18, wherein the first and second conductive elements comprise conductive carbon.

20. The test strip according to claim 19, wherein the enzyme is glucose oxidase.

21. The test strip according to claim 20, wherein the redox mediator is ferricyanide.

22. A method for forming a disposable test strip for use in a test meter ~~of the type~~ which receives a disposable test strip and a sample of blood and performs an electrochemical analysis of the amount of a blood analyte in the sample, comprising:

(a) forming first and second conductive elements on a substrate;

(b) forming a layer of insulation covering the first conductive element, said layer of insulation having a first aperture therein aligned with a portion of the first conductive element in a sample application region; and

(c) forming an integrated reagent/blood separation layer ~~reagent~~ layer disposed on the insulation layer and making contact with the first conductive element through the first aperture in the insulation layer, said integrated reagent/blood separation layer comprising reagents for the electrochemical detection of glucose dispersed in a non-conductive matrix effective to exclude blood cells from the surface of the first conductive element while permitting access to the first conductive species by soluble electroactive species, whereby the first conductive element is isolated from direct contact with a sample placed on the test strip.

23. The method of claim 22, wherein the reagent layer is a non-conductive integrated reagent/blood separation layer.

24. The method of claim 23, wherein the non-conductive integrated reagent/blood separation layer is formed covering the entire first aperture, thereby leaving no portion of the first conductive element directly exposed to a sample applied to the test strip.

25. The method of claim 24, wherein the integrated reagent/blood separation layer comprises an enzyme for oxidation of glucose and a redox mediator effective to transfer electrons from the enzyme to the first conductive element.

26. The method of claim 25, wherein the matrix is formed from silica having both hydrophobic and hydrophilic surfaces.

27. The method of claims 26, wherein the first and second conductive elements comprise conductive carbon.

28. The method according to claim 27, wherein the enzyme is glucose oxidase.

29. The method according to claim 28, wherein the redox mediator is ferricyanide.

30. The method according to claim 24, wherein the integrated reagent/blood separation layer is formed from an aqueous composition comprising 2 to 10 % by weight of a binder; 3 to 10 % by weight of silica; 8 to 20 % by weight of the

redox mediator; and 1000 to 5000 units of the enzyme per gram of the aqueous composition.

31. The method of claims 30, wherein the first and second conductive elements comprise conductive carbon.

32. The method according to claim 30, wherein the enzyme is glucose oxidase.

33. The method according to claim 32, wherein the redox mediator is ferricyanide.

34. The method according to claim 24, wherein the insulation layer is formed over both the first and second conductive elements, and includes a second aperture aligned with the second conductive element.